



Kyrgyzstan: Medical Devices Regulatory Requirements

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Regulatory Agency

The act of registering or re-registering medical use products and medical equipment in Kyrgyzstan is performed by the State Department of Medicine Provision and Medical Equipment under the Ministry of Health of the Kyrgyz Republic.

Registration Procedures

Procedures for registering medical equipment and medical use products are regulated by a law dating from September 16, 1998.

Registration is a requirement for the importation of medical products into Kyrgyzstan. For successful registration, the following documents must be submitted to the State Department of Medicine Provision and Medical Equipment:

- An official letter with the Manufacturer's logo on top addressed to the General Director of the State Department of Medicine Provision and Medical Equipment under the Ministry of Health of the Kyrgyz Republic with the request to register medical use products or equipment;
- Application (standard form: see below)
- Technical specifications or standards, approved by the Ministry of Health of the country of manufacturer
- Registration document from the manufacturer's country (notary signed copy)
- Registration warranty or the right for free sale for the representative organization
- Technical passport with instructions on 'how to use'
- Product Certificate

The application and attached documents should be in 2 copies. The application and all attached documents should be either in Russian or in English and Russian.

The registration procedure should be repeated every 5 years. The cost of registering the medical equipment and medical use products for the first time are:

For small non-electric medical products - \$150

For small electric medical products - \$250

Bigger medical equipment – from \$250 to \$700

The cost of re-registering the medical use products and medical equipment after 5 years would be half of the initial rate.

Medical use products should go through local certification, though certificates issued by foreign authorities may be recognized. Foreign certificates on complex medical equipment usually don't go through the local certification, but they still must be registered.

Sample Application Form:

Application for registration of a medical use product and medical equipment.

1. Medical Equipment or medical use products

Name of the medical equipment or medical use products

Country-manufacturer _____

Company-manufacturer _____

Registration document from the country-manufacturer (#, date, etc.) _____

Scope of use of the medical equipment or medical use products

Address of the company-manufacturer _____

tel. _____ fax. _____

Representative company

Name _____

Address _____

Tel. _____ Fax. _____

Director of the company-applicant _____

Signature, Initials, Last Name

Stamp

Direct Contact at State Department of Medicine Provision and Medical Equipment under the Ministry of Health of the Kyrgyz Republic is:

Jumalieva Nazgul Jumanalievna, Chief of Registration Division

25, 3 Liniya Street (2nd Municipal Hospital), Bishkek, 720000, Kyrgyz Republic

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For more information on Kyrgyzstan, visit BISNIS online at

<http://bisnis.doc.gov/bisnis/country/kyrgyzstan.cfm>

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